Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 16-18 and 22 are pending in the application, with claim 16 being the sole independent claim. Claim 16 is sought to be amended. New claim 22 is sought to be added. Support for the amended and new claims can be found throughout the specification, for example, in Examples 10 and 11. No new matter is added by way of these amendments. It is respectfully requested that the amendments be entered and considered.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

I. Correspondence Address for This Application

The present Office Action was mailed to Mark R. Shanks at Reed Smith, LLP. Applicants note that a Revocation of Prior Power of Attorney and Appointment of New Attorneys of Record was filed in this application on August 30, 2004, requesting that all correspondence be sent to:

Customer Number 26111
Sterne, Kessler, Goldstein & Fox, P.L.L.C.
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934.

A copy of this document is submitted herewith. Applicants request that the correspondence address for this application be updated in the USPTO's records accordingly and that all

future correspondence be sent to the above-noted address for Sterne, Kessler, Goldstein & Fox, P.L.L.C.

II. Nonstatutory Double Patenting Rejections

A. Application Nos. 09/728,207 and 10/444,661

Claim 16 was provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 09/728,207 and claim 1 of copending Application No. 10/444,661. *See* Office Action, pages 3 and 5. Applicants note that Terminal Disclaimers over the '207 and '661 applications were submitted with the Supplemental Amendment and Reply and RCE filed on June 14, 2005. Duplicate copies of the Terminal Disclaimers, along with a date-stamped postcard acknowledging receipt of the Terminal Disclaimers by the USPTO on June 14, 2005, are submitted herewith. Thus, the nonstatutory double patenting rejections based on the '207 and '661 applications have been fully accommodated and should be withdrawn.

B. Application Nos. 09/720,003 and 09/720,979

The rejections of claim 16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 09/720,003 and claims 1-6, 8-10 and 14-18 of copending Application No.09/720,972, have been withdrawn. *See* Office Action, pages 4-5.

III. Claim Rejection Under 35 U.S.C. § 112, First Paragraph -- Enablement

Claims 16-18 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. *See* Office Action, page 6. According to the Examiner, "The breadth of these claims is overly broad . . . because Applicant's claimed proteins and genera are not reasonably predicted to protect any brain cells from any animal from ischemia." *See* Office Action, page 7. The Examiner has focused the enablement rejection on the supposed unpredictability of gene therapy. In the Examiner's words, "even if a single method of administration is effective with a particular type of transgene and vector, it is not reasonably predictable that another transgene or method of administration would be effective, due to the very nature of gene therapy." *See* Office Action, page 9. Applicants respectfully submit that the Examiner's comments do not support a rejection for lack of enablement because the present claims are directed to vectors, not to gene therapy methods. Thus, the Examiner's comments regarding the supposed difficulties associated gene therapy methods are irrelevant to an assessment of the enablement of the currently claimed vectors.

The Examiner has apparently acknowledged that the claims are directed to vectors and not to methods, but nonetheless asserted that:

> Applicant may argue that they only wish to obtain viral vectors, and therefore, the claims should be allowed for their full scope. However, Applicant's specification is particularly directed to the use of such vectors in transforming pyramidal cells of the hippocampus (e.g., p. 20, paragraph 2), and therefore, such use must be considered.

See Office Action, page 19. Applicants respectfully remind the Examiner that, when a claim is directed to a composition and does not recite a particular use, then *any* enabled use of the composition is sufficient to satisfy the how-to-use prong of the enablement requirement. As stated in the M.P.E.P.:

> [W]hen a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use.

See M.P.E.P. § 2164.01(c). The present specification provides working examples showing uses of vectors of the invention. In particular, examples 2 to 11 demonstrate that Sendai virus (SeV) vectors were introduced to various nerve cells *in vitro* or *in vivo*, the foreign genes were expressed, and the expression products were proven to function. In view of these working examples, it must be concluded that the how-to-use prong of the enablement requirement is fully satisfied with respect to the present claims.

The Examiner's attention is directed to the USPTO's Training Materials For Examining Patent Applications With Respect to 35 U.S.C. § 112, First Paragraph -- Enablement Chemical/Biotechnical Applications, Example G (available at http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm; copy submitted herewith as Exhibit 1). This Example assesses the enablement of a viral vector claim that does not include a particular use limitation. The specification in this hypothetical Example includes *in vitro* working examples with representative samples of viral vectors, genes of interest and cells,

but does not show any examples relating to gene therapy or any *in vivo* use of the viral vectors. It is nonetheless concluded that the vector claim is adequately enabled. According to the Analysis set forth in this Example:

> The specification discloses an *in vitro* use for the viral vector of claim 1 and clearly discloses how to make and use the viral vector in the *in vitro* environment. Since claim 1 does not recite any environment of use, only one enabled use covering the scope of the claim is needed to enable the claim. Therefore, the disclosure with respect to the *in vitro* use of the viral vectors is sufficient to enable claim 1 and it would be inappropriate to include claim 1 in a rejection under 35 U.S.C. 112, first paragraph.

See Training Materials, page 2.

Since the present specification clearly discloses how to make and use the claimed viral vectors in the *in vitro* environment, it is improper for the Examiner to base the enablement rejection on the supposed difficulties associated with gene therapy in general or the asserted unpredictability of introducing SeV vectors to pyramidal cells of the hippocampus in particular. Thus, Applicants respectfully submit that the present claims are fully enabled. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicants believe that the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Supplemental Amendment and Reply is respectfully requested.

Respectfully submitted,

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Date: JAN. 05, 2006

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